FEDERAL REGISTER

VOLUME 3 NUMBER 251

Washington, Wednesday, December 28, 1938

The President

EXECUTIVE ORDER

CHANGING THE TITLE OF EXECUTIVE DIRECTOR OF NATIONAL YOUTH ADMINISTRATION TO ADMINISTRATOR OF THE NATIONAL YOUTH ADMINISTRATION

By virtue of and pursuant to the authority vested in me as President of the United States, it is hereby ordered that the title of the officer appointed and designated to have the immediate supervision of the National Youth Administration be changed from Executive Director to Administrator of the National Youth Administration.

FRANKLIN D ROOSEVELT

THE WHITE HOUSE,
December 24, 1938.

[No. 8028]

[F. R. Doc. 38-3898; Filed, December 27, 1938; 10:18 a. m.]

Rules, Regulations, Orders

TITLE 21—FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

PROMULGATION OF REGULATIONS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND REPEAL OF CERTAIN REGULATIONS HERETOFORE PROMULGATED THEREUNDER

Under the authority of section 701 (a) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040 et seq.; 21 U. S. C. 301 et seq.), the following regulations for the enforcement of the Act are hereby promulgated.

These regulations shall take effect on June 25, 1939; except that, to the extent that they may relate to the enforcement of sections 502 (j), 505, or 601 (a) of the Act, they shall take effect on the date hereof.

The regulations[1] under sections 201 (p), 505, and 702 (b) of the Act, which were promulgated on July 22, 1938, are hereby repealed effective on the date hereof.

December 22, 1938.

[SEAL] H. A. WALLACE,
Secretary of Agriculture.

[1] 3 F. R. 1846 DI.

REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

GENERAL REGULATION

(a) The provisions of regulations promulgated under the Act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in section 201 of the Act shall be applicable also to such terms when used in regulations promulgated under the Act.

(The caption of each of the following regulations designates the section of the Act under which the regulation is issued.)

SECTION 201 (M)

Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

SECTION 201 (N)

The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

SECTION 201 (P)

Newness of a drug may arise by reason (among other reasons) of—

(1) the newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component;

(2) the newness for drug use of a combination of two or more substances, none of which is a new drug:

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RULES, REGULATIONS, ORDERS

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FEDERAL REGISTER

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(3) the newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug;

(4) the newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body; or

(5) the newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

SECTION 301 (H)

In case of the giving of a guaranty or undertaking referred to in section 303 (c) (2) or (3) of the Act, each person signing such guaranty or undertaking shall be considered to have given it.

SECTION 303 (C)

(a) A guaranty or undertaking referred to in section 303 (c) (2) of the Act may be—

(1) limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery; or

(2) general and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303 (c) (2) of the Act:

(1) (Limited Form for use on invoice or bill of sale)

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404 or 505 of the Act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking)

(2) (General and Continuing Form)

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or on the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404 or 505 of the Act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking)

(c) The application of a guaranty or undertaking referred to in section 303 (c) (2) of the Act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the Act, or becomes an article which may not, under the provisions of section 404 or 505 of the Act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303 (c) (3) of the Act shall state that the shipment or other delivery of coal-tar color covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303 (c) (3) of the Act:

(1) (For domestic manufacturers)

(Name of manufacturer) hereby guarantees that all coal-tar colors listed herein were manufactured by him, and are from batches certified in accordance with the applicable regulations promulgated by the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer).

(2) (For foreign manufacturers)

(Name of manufacturer and agent) hereby severally guarantee that all coal-tar colors listed herein were manufactured by (name of manufacturer), and are from batches certified in accordance with the applicable regulations promulgated by the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer)

(Signature and post-office address of agent)

(f) For the purpose of a guaranty or undertaking under section 303 (c) (3) of the Act the manufacturer of a shipment or other delivery of a coal-tar color is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the Act shall be made in labeling.

SECTION 305

(a) Presentation of views under section 305 of the Act shall be private and informal. The views presented shall be confined to matters relevant to the contemplated proceeding. Such views may be presented by letter or in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking referred to in section 303 (c) (2) or (3) of the Act applicable to the article on which such notice was based, such guaranty or undertaking, or a verified copy thereof, shall be made a part of such presentation of views.

(b) Upon request, seasonably made, by the person to whom a notice appointing a time and place for the presentation of views under section 305 of the Act has been given, or by his representative, such time or place, or both such time and place, may be changed if the request states reasonable grounds therefor. Such request shall be addressed to the office of the Food and Drug Administration which issued the notice.

SECTION 403 (A)

(a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

SECTION 403 (E)

(a) If a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such food, such as "Manufactured for and Packed by ———", "Distributed by ———", or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such food was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any food from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of food in the package, exclusive of wrappers and other material packed with such food.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such food and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and, except in case of frozen food which is so consumed, shall express the volume at 68° Fahrenheit (20° Centigrade). A statement of dry measure shall be in terms of the United States bushel of 2150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof; or in terms of the United States standard barrel and its subdivisions of third, half, and three-quarters barrel. However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subdivison (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of food in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of the food as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the food. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of food in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (f) of this regulation, and which is applicable to such food under the provisions of paragraph (e) (2) of this regulation, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one quart of food shall be "1 quart", and not "2 pints" or "32 fluid ounces"), unless the statement is made in accordance with the provisions of subdivision (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in small units, if any smaller is specified in such paragraph (f) (for examples, 1¾ quarts may be expressed as "1 quart 1½ pints" or 1 quart 1 pint 8 fluid ounces"; 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for examples, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1½ pounds" or "1 pound 8 ounces").

(2) In the case of a food with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity—

(1) variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice.

But under subdivision (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this regulation in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A food shall be exempt from compliance with the requirements of clause (2) of section 403 (e) of the Act if—

(1) the quantity of the contents, as expressed in terms applicable to such food under the provisions of paragraph (e) (2) of this regulation, is less than one-half ounce avoirdupois, or less than

one-half fluid ounce, or (in case the units of the food can be easily counted without opening the package) less than six units; or

(2) the statement of the quantity of the contents of the package, together with all other words, statements, and information required by or under authority of the Act to appear on the label, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 403 (f) of the Act and regulations promulgated thereunder.

SECTION 403 (F)

(a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by section 403 (f) of the Act by reason (among other reasons) of—

(1) the failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) the failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 403 (e) or (i) of the Act, shall apply if such insufficiency is caused by—

(1) the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(2) the use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 403 (f) of the Act; or

(3) the use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

SECTION 403 (I)

(a) The name of an ingredient (except a spice, flavoring, or coloring which is an ingredient of a food other than one sold as a spice, flavoring, or coloring), required by section 403 (i) (2) of the Act to be borne on the label of a food, shall be a specific name and not a collective name. But if an ingredient (which itself contains two or more ingredients) conforms to a definition and standard of identity prescribed by regulations under section 401 of the Act, such ingredient may be designated on the label of such food by the name specified in the definition and standard, supplemented, in case such regulations require the naming of optional ingredients present in such ingredient, by a statement showing the optional ingredients which are present in such ingredient.

(b) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be, within the meaning of such term as commonly understood by consumers. The term "coloring" shall not include any bleaching substance.

(c) An ingredient which is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as spice and coloring, or flavoring and coloring, as the case may be, unless such ingredient is designated by its specific name.

(d) A label may be misleading by reason (among other reasons) of—

(1) the order in which the names of ingredients appear thereon, or the relative prominence otherwise given such names; or

(2) its failure to reveal the proportion of, or other fact with respect to, an ingredient, when such proportion or other fact is material in the light of the representation that such ingredient was used in fabricating the food.

(e) (1) A food shall be exempt from the requirements of clause (2) of section 403 (i) of the Act if all words, statements, and other information required by or under authority of the Act to appear on the label of such food, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 403 (f) of the Act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by regulation (m) (2) under section 403 (e) of the Act, and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) In the case of an assortment of different items of food, when variations in the items which make up different packages packed from such assortment normally occur in good packing practice, and when such variations result in variations in the ingredients in different packages, such food shall be exempt from compliance with the requirements of clause (2) of section 403 (i) of the Act with respect to any ingredient which is not common to all packages. But such exemption shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement in terms which are as informative as practicable and which are not misleading, indicating that other ingredients may be present.

SECTION 403 (K)

(a) (1) The term "artificial flavoring" means a flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

(2) The term "artificial coloring" means a coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

(3) The term "chemical preservative" means any chemical which, when added to food, tends to prevent or retard deterioration thereof; but does not include common salt, sugars, vinegars, spices or oils extracted from spices, or substances added to food by direct exposure thereof to wood smoke.

(b) A food which is subject to the requirements of section 403 (k) of the Act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read

by the ordinary individual under customary conditions of purchase and use of such food.

(d) A food shall be exempt from compliance with the requirements of section 403 (k) of the Act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

SECTION 405

(a) (1) An open container is a container of rigid or semi-rigid construction, which is not closed by lid, wrapper, or otherwise.

(2) An open container of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than one dry quart, shall be exempt from the labeling requirements of paragraphs (e), (g) (2) (with respect to the name of the food specified in the definition and standard), and (i) (1) of section 403 of the Act; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of such containers enclosed therein and the quantity of the contents of each.

(b) Except as provided by paragraphs (c) and (d) of this regulation, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (j) and (k) of the Act if—

(1) the person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) in case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will insure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator, shall each keep a copy of such agreement until all of such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(c) An exemption of a shipment or other delivery of a food under clause (1) of paragraph (b) of this regulation shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(d) An exemption of a shipment or other delivery of food under clause (2) of paragraph (d) of this regulation shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(e) An exemption of a shipment or other delivery of a food under clause (2) of paragraph (b) of this regulation shall expire—

(1) at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

(2) upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

SECTION 501 (B)

(a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term "drug defined in an official compendium" means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.

SECTION 502 (A)

(a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic.

(b) The labeling of a drug which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

SECTION 502 (B)

(a) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as "Manufactured for and Packed by ————," "Distributed by ————," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of such drug in the package, exclusive of wrappers and other material packed with such drug.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers and users of such drug to express quantity thereof and which give accurate information as to such quantity. But if no general usage in expressing accurate information as to the quantity of such drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampul, or other unit form shall be in terms of weight if the drug is solid, semisolid, or viscous, or in terms of measure if the drug is liquid; the statement of the quantity of a drug which is in such unit form shall be in terms of the numerical count of such units, supplemented, when necessary to give accurate information as to the quantity of such drug in the package, by such statement (in such terms, manner, and form as are not misleading) of the weight or measure of such units, or of the quantity of each active ingredient in each such unit, as will give such information.

(3) The statement of the quantity of a device shall be expressed in terms of numerical count.

(f) A statement of weight shall be in terms of the avoirdupois pound, ounce,

and grain, or of the kilogram, gram, and milligram. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, fluid ounce, and fluidram subdivisions thereof, or of the liter, milliliter, or cubic centimeter, and shall express the volume at 68° Fahrenheit (20° Centigrade).

(g) Statements of the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(h) (1) Unless made in accordance with the provisions of subdivision (2) of this paragraph, a statement of the quantity of a drug, in the terms of weight or measure applicable to such drug under the provisions of paragraph (e) (2) of this regulation, shall express the number of the largest unit specified in paragraph (f) of this regulation which is contained in the package (for example, the statement on the label of a package which contains one pint of a drug shall be "1 pint," and not "16 fluid ounces"). Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for example, 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for example, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint").

(2) In the case of a drug with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement of the quantity of a drug or device shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement, except in the case of ampuls, shall be considered to express the average quantity. The statement of the quantity of a drug in ampuls shall be considered to express the minimum quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large. In the case of a liquid drug in ampuls the variation above the stated measure shall comply with the excess volume prescribed by the National Formulary for filling of ampuls.

(k) Where the statement does not express the minimum quantity—

(1) variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) variations from the stated weight, measure, or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting the contents of individual packages which occur in good packing practice.

But under subdivision (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this regulation in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A drug or device shall be exempt from compliance with the requirements of clause (2) of section 502 (b) of the Act if—

(1) the statement of the quantity of the contents, as expressed in terms applicable to such drug or device under the provisions of paragraph (e) (2) of this regulation, together with all other words, statements, and information required by or under authority of the Act to appear on the label of such drug or device, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 502 (c) of the Act and regulations promulgated thereunder; or

(2) the quantity of the contents of the package, as expressed in terms of numerical count in compliance with paragraph (e) (2) or (3) of this regulation, is less than six units, and such units can be easily counted without opening the package.

SECTION 502 (C)

(a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by section 502 (c) of the Act by reason (among other reasons) of—

(1) the failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) the failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502 (b) or (c) of the Act, shall apply if such insufficiency is caused by—

(1) the use of label space for any word statement, design, or device which is not required by or under authority of the Act to appear on the label;

(2) the use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502 (c) of the Act; or

(3) the use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and their information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

SECTION 502 (d)

(a) (1) The name of a substance or derivative required by or under authority of section 502 (d) of the Act to be borne on the label of a drug shall be the name by which such substance is designated in such section 502 (d), or such derivative is designated in regulations promulgated thereunder.

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in section 502 (d) of the Act, shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) (1) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) The statement of the percentage of such substance or derivative contained in a drug shall express the percentage by weight; except that, if both the substance or derivative and the drug are liquid, the statement may express the percentage by volume at 68° Fahrenheit (20° Centigrade), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(c) The names, quantities, and percentages of all such substances and derivatives, and the statement "Warning—May be habit forming," shall immediately follow (without intervening written, printed, or graphic matter) the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded under section 502 (d) of the Act by reason of failure of its label to bear the statement "Warning—May be habit forming," if such drug is not suitable for internal use and is distributed and sold exclusively for such external use as involves no possibility of habit formation.

SECTION 502 (e)

(a) (1) The name of an ingredient, substance, derivative, or preparation required by section 502 (e) (2) of the Act to be borne on the label of a drug shall be the name thereof which is listed in such section 502 (e) (2), or, if not so listed, shall be a specific name and not a collective name. But if an ingredient (which itself contains two or more such ingredients, substances, derivatives, or preparations) complies with the specifications set forth for an article in an official compendium, such ingredient may be designated on the label of such drug by the common or usual name under which such specifications are so set forth.

(2) An abbreviation or chemical formula shall not be considered to be a common or usual name. The name "acetophenetidin" shall be considered to be the same as the name "acetphenetidin", "aminopyrine" the same as "amidopyrine." The name "alcohol," without qualification, means ethyl alcohol.

(b) (1) A derivative or preparation of a substance named in section 502 (e) (2) of the Act is an article which is derived or prepared from such substance by any method, including actual or theoretical chemical action.

(2) A statement on the label of a drug of the name of a constituent thereof, which constituent is a derivative or preparation of a substance named in section 502 (e) (2) of the Act, shall show the substance from which such constituent is derived or prepared and that such constituent is a derivative or preparation thereof.

(c) (1) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of a substance, derivative, or preparation contained therein shall express the weight or measure of such substance, derivative, or preparation in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance, derivative, or preparation in a specified unit of weight or measure of the drug, or the percentage of such substance, derivative, or preparation in such drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) A statement of the percentage of alcohol shall express the percentage of absolute alcohol at 68° Fahrenheit (20° Centigrade). A statement of the percentage of a substance, derivative, or preparation other than alcohol shall express the percentage by weight; except that, if both the substance, derivative, or preparation and the drug containing it are liquid, the statement may express the percentage by volume at 68° Fahrenheit (20° Centigrade), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(d) In case a statement of the quantity or proportion of a derivative or preparation in a drug is not as informative, to consumers or users of such drug, of the activity or consequences of use thereof as a statement of the quantity or proportion of the substance from which such derivative or preparation is derived or prepared, the quantity or proportion of such substance shall also be stated on the label of such drug.

(e) A label of a drug may be misleading by reason (among other reasons) of—

(1) the order in which the names of ingredients, substances, derivatives, or preparations appear thereon, or the relative prominence otherwise given such names; or

(2) its failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative, or preparation, when such proportion or other fact is material in the light of the representation that such ingredient, substance, derivative, or preparation is a constituent of such drug.

(f) (1) A drug shall be exempt from the requirements of clause (2) of section 502 (e) of the Act if all words, statements, and other information required by or under authority of the Act to appear on the label of such drug, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 502 (e) of the Act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by regulation (m) (1) under section 502 (b) of the Act, and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) A drug shall be exempt from the requirements of clause (2) of section 502 (e) of the Act with respect to the alkaloids atropine, hyoscine or hyoscyamine contained in such drug, if such alkaloid is contained therein as a constituent of belladonna, hyoscyamus, acopola, stramonium, or other plant material, or any preparation thereof, which was used as an ingredient of such drug, and no practical and accurate method of analysis exists for the quantitative determination of each such alkaloid in such ingredient. But such exemption shall be on the condition that the label of such drug shall state the quantity or proportion of total alkaloids contained therein as constituents of such ingredient.

SECTION 502 (f)

(a) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part, or incorrect specification of—

(1) directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any there be, for which such drug or device is commonly and effectively used;

(2) quantity of dose (including quantities for persons of different ages and different physical conditions;

(3) frequency of administration or application;

(4) duration of administration or application;

(5) time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factor);

(6) route or method of administration or application; or

(7) preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

(b) A shipment or other delivery of a drug or device shall be exempt from compliance with the requirements of clause (1) of section 502 (f) of the Act—

(1) with respect to directions for common uses, adequate directions for which are known by the ordinary individual;

(2) if the label of such drug or device bears the statement *"Caution: To be used only by or on the prescription of a ——"* (the blank to be filled in by the word *"Physician"*, *"Dentist"*, or *"Veterinarian"*, or any combination of such words), and all representations or suggestions contained in the labeling thereof with respect to the conditions for which such drug or device is to be used appear only in such medical terms as are not likely to be understood by the ordinary individual, and if such shipment or delivery is made for use exclusively by, or on the prescription of, physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device; but such exemption shall expire when such shipment or delivery, or any part thereof, is offered or sold or otherwise disposed of for any use other than by or on the prescription of such a physician, dentist, or veterinarian, except such use as renders the article not a drug or device within the meaning of section 201 (g) and (h) of the Act; or

(3) if the label of such drug or device bears the statement *"For manufacturing use only"*, and the labeling thereof contains no representation or suggestion with respect to the effect of such drug or device, and if such shipment or delivery is made for use exclusively in the manufacture of another drug or device; but such exemption shall expire when such shipment or delivery, or any part thereof, is offered or sold or otherwise disposed of for any use other than in such manufacture, except such use as renders the article not a drug or device within the meaning of section 201 (g) and (h) of the Act.

(c) The expiration of an exemption under paragraph (b) of this regulation shall not be considered to render invalid the exemption existing up to the time of expiration. The causing by any person of such exemption so to expire shall be considered to be an act of misbranding for which such person shall be liable.

SECTION 503 (A)

(a) Except as provided by paragraphs (b) and (c) of this regulation, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501 (b) and 502 (b), (d), (e), (f), and (g) of the Act if—

(1) the person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or

(2) in case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(b) An exemption of a shipment or other delivery of a drug or device under clause (1) of paragraph (a) of this regulation shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(c) An exemption of a shipment or other delivery of a drug or device under clause (2) of paragraph (d) of this regulation shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(d) An exemption of a shipment or other delivery of a drug or device under clause (2) of paragraph (a) of this regulation shall expire—

(1) at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

(2) upon refusal by the operator of the establishment where such drug or device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

SECTION 505 (A)

A new drug shall not be deemed to be subject to section 505 of the Act if it is a drug which is licensed under the Virus, Serum, and Toxin Act of July 1, 1902 (U. S. C., 1934 ed., title 42, ch. 4), or the Virus, Serums, Toxins, Antitoxins and Analogous Products Act of March 4, 1913 (U. S. C., 1934 ed., title 21, ch. 5).

SECTION 505 (B)

An application which is on its face incomplete in that it does not contain all the matter required by clauses (1), (2), (3), (4), and (6) of section 505 (b) of the Act shall not be accepted for filing; the Food and Drug Administration shall notify the applicant of such non-acceptance and shall specify the clauses in respect of which such application is on its face incomplete. Otherwise the date on which an application is received by the Department shall be considered to be the date on which such application is filed, and the Food and Drug Administration shall notify the applicant of such date. If the applicant withdraws his application, such application shall be considered as not having been filed.

SECTION 505 (C)

If the Secretary determines, before the date prescribed by section 505 (c) of the Act for an application to become effective, that he has no cause to issue an order under section 505 (d) of the Act refusing to permit such application to become effective, the Food and Drug Administration shall so notify the applicant in writing and such application shall become effective on the date of the notification.

SECTION 505 (I)

A shipment or other delivery of a new drug shall be exempt from the operation of section 505 (a) of the Act if—

(1) the label of such drug bears the statement "For investigational use only.";

(2) such shipment or delivery is made only to, and solely for investigational use by, an expert qualified by scientific training and experience to investigate the safety of drugs; and

(3) the person who introduced such shipment or delivery into interstate commerce holds a signed statement from such expert to the effect that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation, unless and until an application under section 505 (b) of the Act becomes effective with respect to such drug.

SECTION 601 (A)

The term "coal-tar hair dye" includes all articles containing any coal-tar color or intermediate which color or interme-

diate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

SECTION 602 (A)

(a) Among representations in the labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug, or device.

(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

SECTION 602 (B)

(a) If a cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such cosmetic, such as "Manufactured for and Packed by ------", "Distributed by ----", or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a cosmetic at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such cosmetic was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any cosmetic from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of cosmetic in the package, exclusive of wrappers and other material packed with such cosmetic.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such cosmetic and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such cosmetic exists, the statement shall be in terms of liquid measure if the cosmetic is liquid, or in terms of weight if the cosmetic is solid, semisolid, or viscous, or in such terms of numerical count, or numerical count and weight or measure, as will give accurate information as to the quantity of the cosmetic in the package.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall express the volume at 68° Fahrenheit (20° Centigrade). However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subdivision (1) of his paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of cosmetic in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of the cosmetic as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the cosmetic. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of cosmetic in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (f) of this regulation, and which is applicable to such cosmetic under the provisions of paragraph (e) (2) of this regulation, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one pint of cosmetic shall be "1 pint" and not "16 fluid ounces"), unless the statement is made in accordance with the provisions of subdivision (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for examples, 1¾ quarts may be expressed as "1 quart 1½ pints" or "1 quart 1 pint 8 fluid ounces"; 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for examples, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1½ pounds" or "1 pound 8 ounces").

(2) In the case of a cosmetic with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the package. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity—

(1) variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice.

But under subdivision (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the cosmetic is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this regulation in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A cosmetic shall be exempt from compliance with the requirements of clause (2) of section 602 (b) of the Act if the quantity of the contents of the package, as expressed in terms applicable to such cosmetic under the provisions of paragraph (e) (2) of this regulation, is less than one-fourth ounce avoirdupois, or less than one-eighth fluid ounce, or (in case the units of the cosmetic can be easily counted without opening the package) less than six units.

SECTION 602 (C)

(a) A word, statement, or other information required by or under authority of

the Act to appear on the label may lack that prominence and conspicuousness required by section 602 (c) of the Act by reason (among other reasons) of—

(1) the failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) the failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

SECTION 603

(a) Except as provided by paragraphs (b) and (c) of this regulation, a shipment or other delivery of a cosmetic which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of sections 601 (a) and 602 (b) of the Act if—

(1) the person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such cosmetic is to be processed, labeled, or repacked; or

(2) in case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling or repacking, as the case may be, of such cosmetic in such establishment as will insure, if such specifications are followed, that such cosmetic will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(b) An exemption of a shipment or other delivery of a cosmetic under clause (1) of paragraph (a) of this regulation shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(c) An exemption of a shipment or other delivery of a cosmetic under clause (2) of paragraph (d) of this regulation shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(d) An exemption of a shipment or other delivery of a cosmetic under clause (2) of paragraph (a) of this regulation shall expire—

(1) at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

(2) upon refusal by the operator of the establishment where such cosmetic is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

SECTION 702 (B)

(a) (1) When any officer or employee of the Department collects a sample of a food, drug, or cosmetic for analysis under the Act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Department indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee of the Department shall be considered to be official samples.

(2) For the purpose of determining whether or not a sample is collected for analysis, the term "analysis" includes examinations and tests.

(3) The owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

(b) When an officer or employee of the Department collects an official sample of a food, drug, or cosmetic for analysis under the Act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless—

(1) the amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated;

(2) the cost of twice the quantity so estimated exceeds $10;

(3) the article is perishable;

(4) the sample is collected from a shipment or other lot which is being imported or offered for import into the United States;

(5) the sample is collected from a person named on the label of the article, or his agent, and such person is also the owner of the article;

(6) the sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon; or

(7) the analysis consists principally of rapid analytical procedures, organoleptic examination, or other field inspection examinations or tests, made at the place where the sample is collected or in a mobile or temporary laboratory.

In addition to the quantity of sample prescribed above the officer or employee shall, if practicable, collect as part of the sample such further amount of the article as he estimates to be sufficient for use as exhibits in the trial of any case that may arise under the Act based on the sample.

(c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the Act, or otherwise subject to the prohibitions of the Act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the Act based on the sample, a part of the sample, if any remains available, shall be provided for

analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except when—

(1) after collection, the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or

(2) the request is not made within a reasonable time before the trial of any case under the Act, based on the sample, to which such person or owner is a party.

The person, owner, attorney, or agent who requests the part of sample shall specify the amount desired and make advance payment of the cost thereof. A request from an owner shall be accompanied by a showing of ownership, and a request from an attorney or agent by a showing of authority from such person or owner to receive the part of sample. When two or more requests for parts of the same sample are received the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefor.

(d) When an official sample of a food, drug, or cosmetic is the basis of a notice given under section 305 of the Act, or of a case under the Act, and the person to whom the notice was given, or any person who is a party to the case, has no right under paragraph (c) of this regulation to a part of the sample, such person or his atttorney or agent may obtain a part of the sample upon request accompanied by a written waiver of right under such paragraph (c) from each person named on the label of the article and owner thereof, who has not exercised his right under such paragraph (c). The operation of this paragraph shall be subject to the exceptions, terms, and conditions prescribed in paragraph (c) of this regulation.

(e) The Food and Drug Administration is authorized to destroy—

(1) any official sample when it determines that no analysis of such sample will be made;

(2) any official sample or part thereof when it determines that no notice under section 305 of the act, and no case under the Act, is or will be based on such sample;

(3) any official sample or part thereof when the sample was the basis of a notice under section 305 of the Act, and when, after opportunity for presentation of views following such notice, it determines that no other such notice, and no case under the Act, is or will be based on such sample;

(4) any official sample or part thereof when the sample was the basis of a case under the Act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample;

(5) any official sample or part thereof if the article is perishable;

(6) any official sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for analysis;

(7) that part of any official sample which is in excess of three times the quantity it estimates to be sufficient for analysis.

[F. R. Doc. 38-3897; Filed, December 23, 1938; 12:39 p. m.]

TITLE 7—AGRICULTURE

SUGAR DIVISION

[General Sugar Quota Regulations, Series 6, No. 1]

Sugar Consumption Requirements and Quotas for Calendar Year 1939

December 23, 1938.

By virtue of the authority vested in the Secretary of Agriculture by the Sugar Act of 1937, approved September 1, 1937, I, H. A. Wallace, Secretary of Agriculture, in order to carry out the powers vested in me by the said act, do hereby make, prescribe, publish, and give public notice of these regulations, which shall have the force and effect of law and shall remain in force and effect until amended or superseded by orders or regulations hereafter made by the Secretary of Agriculture.

Sec. 821.21 *Consumption requirements for 1939.* It is hereby determined, pursuant to Section 201 of the Sugar Act of 1937 (hereinafter referred to as the "act"), that the amount of sugar needed to meet the requirements of consumers in the continental United States for the calendar year 1939 is 6,832,157 short tons of sugar, raw value. (Sec. 201, 50 Stat. 904; 7 U. S. C., Sup. III, 1111)

Sec. 821.22 *Quotas for domestic areas.* (a) *Original quotas.* There are hereby established, pursuant to section 202 of the said act, for domestic sugar-producing areas, for the calendar year 1939, the following quotas:

Area:	*Quotas in terms of short tons, raw value*
Domestic beet sugar	1,584,524
Mainland cane sugar	429,553
Hawaii	958,994
Puerto Rico	815,810
Virgin Islands	9,115

(Sec. 202, 50 Stat. 905; 7 U. S. C., Sup. III, 1112)

Sec. 821.23 *Other quotas*—(a) *Original quotas.* There are hereby established, pursuant to section 202 of the said act, for foreign countries and the Commonwealth of the Philippine Islands, for the calendar year 1939, the following quotas:

Area:	*Quotas in terms of short tons, raw value*
Commonwealth of the Philippine Islands	1,052,854
Cuba	1,954,303
Foreign countries other than Cuba	27,004

(Sec. 202, 50 Stat. 905; 7 U. S. C., Sup. III, 1112)

Sec. 821.24 *Proration of quota for foreign countries other than Cuba.* (a) *Original prorations.* The quota for foreign countries other than Cuba is hereby prorated, pursuant to section 202 of the said act, among such countries as follows:

Country:	*Prorations in pounds*
Argentina	15,771
Australia	221
Belgium	318,423
Brazil	1,295
British Malaya	28
Canada	610,433
China & Hongkong	311,721
Colombia	289
Costa Rica	22,285
Czechoslovakia	284,875
Dominican Republic	7,214,853
Dutch East Indies	228,704
Dutch West Indies	7
France	189
Germany	126
Guatemala	362,342
Haiti, Republic of	997,126
Honduras	3,713,814
Italy	1,895
Japan	4,337
Mexico	6,526,095
Netherlands	235,716
Nicaragua	11,058,456
Peru	12,024,728
Salvador	8,881,104
United Kingdom	379,399
Venezuela	313,763
Sub-total	53,508,000
Unallotted reserve	500,000
Total	54,008,000

(Sec. 202, 50 Stat. 905; 7 U. S. C., Sup. III, 1112)

Sec. 821.25 *Direct consumption portion of quotas.* (a) *Domestic areas.* The quotas established in Sec. 821.22 hereof for the following listed areas may be filled by direct consumption sugar not in excess of the following amount for each such area:

Area:	*Amount of direct consumption sugar in terms of short tons, raw value*
Hawaii	29,616
Puerto Rico	126,033
Virgin Islands	0

(b) *Other areas.* The quotas established in Sec. 821.23 hereof for the following listed areas may be filled by direct consumption sugar not in excess of the following amount for each such area:

Area:	*Amount of direct consumption sugar in terms of short tons, raw value*
Commonwealth of the Philippine Islands	80,214
Cuba	375,000

(Sec. 207, 50 Stat. 907; 7 U. S. C., Sup. III, 1117)

Sec. 821.26 *Liquid sugar quotas.* There are hereby established, pursuant to section 208 of the said act, for foreign countries, for the calendar year 1939, quotas for liquid sugar as follows:

Country:	*In terms of wine gallons of 72% total sugar content*
Cuba	7,970,556
Dominican Republic	830,894
Other foreign countries	0

(Sec. 208, 50 Stat. 908; 7 U. S. C., Sup. III, 1118)

SEC. 821.27 *Restrictions on marketing and shipment.* (a) For the calendar year 1939, all persons are hereby forbidden, pursuant to section 209 of the said act, from bringing or importing into the continental United States from the Territory of Hawaii, Puerto Rico, the Virgin Islands, the Commonwealth of the Philippine Islands, or any foreign country, any sugar or liquid sugar after the quota for such area, or the proration of any such quota, has been filled.

(b) For the calendar year 1939, all persons are hereby forbidden, pursuant to section 209 of the said act, from shipping, transporting or marketing in interstate commerce, or in competition with sugar or liquid sugar shipped, transported, or marketed in interstate or foreign commerce, any sugar or liquid sugar produced from sugar beets or sugarcane grown in either the domestic beet sugar area or the mainland cane sugar area after the quota for such area has been filled. (Sec. 209, 50 Stat. 906; 7 U. S. C., Sup. III, 1119)

SEC. 821.28 *Inapplicability of quota regulations.* These regulations (Secs. 821.21–821.27) shall not apply to (1) the first 10 tons, raw value, of sugar or liquid sugar imported from any foreign country, other than Cuba; (2) the first 10 tons, raw value, of sugar or liquid sugar imported from any foreign country, other than Cuba, for religious, sacramental, educational, or experimental purposes; (3) liquid sugar imported from any foreign country, other than Cuba, in individual sealed containers not in excess of one and one-tenth gallons each; or (4) any sugar or liquid sugar imported, brought into, or produced or manufactured in, the United States for the distillation of alcohol, or for livestock feed, or for the production of livestock feed. (Sec. 212, 50 Stat. 909; 7 U. S. C., Sup. III, 1122)

In testimony whereof, I have hereunto set my hand and caused the official seal of the Department of Agriculture to be affixed in the District of Columbia, city of Washington, this 23d day of December, 1938.

[SEAL] H. A. WALLACE,
Secretary of Agriculture.

[F. R. Doc. 38-3907; Filed, December 27, 1938; 12:18 p. m.]

DETERMINATION OF PROPORTIONATE SHARES FOR FARMS IN DOMESTIC BEET SUGAR AREA FOR 1939 CROP

DECEMBER 23, 1938.

Whereas Section 302 of the Sugar Act of 1937 provides in part as follows:

(a) The amount of sugar or liquid sugar with respect to which payment may be made shall be the amount of sugar or liquid sugar commercially recoverable, as determined by the Secretary, from the sugar beets or sugarcane grown on the farm and marketed (or processed by the producer) not in excess of the proportionate share for the farm, as determined by the Secretary, of the quantity of sugar beets or sugarcane for the extraction of sugar or liquid sugar required to be processed to enable the producing area in which the crop of sugar beets or sugarcane is grown to meet the quota (and provide a normal carry-over inventory) estimated by the Secretary for such area for the calendar year during which the larger part of the sugar or liquid sugar from such crop normally would be marketed.

(b) In determining the proportionate shares with respect to a farm, the Secretary may take into consideration the past production on the farm of sugar beets and sugarcane marketed (or processed) for the extraction of sugar or liquid sugar and the ability to produce such sugar beets or sugarcane, and the Secretary shall, insofar as practicable, protect the interests of new producers and small producers and the interests of producers who are cash tenants, share-tenants, adherent planters, or share-croppers.

and

Whereas subsection (c) of section 301 of said act provides, as one of the conditions for payment to producers of sugar beets and sugarcane, as follows:

(c) That there shall not have been marketed (or processed) an amount (in terms of planted acreage, weight, or recoverable sugar content) of sugar beets or sugarcane grown on the farm and used for the production of sugar or liquid sugar to be marketed in, or so as to compete with or otherwise directly affect interstate or foreign commerce, in excess of the proportionate share for the farm, as determined by the Secretary pursuant to the provisions of section 302, of the total quantity of sugar beets or sugarcane required to be processed to enable the area in which such sugar beets or sugarcane are produced to meet the quota (and provide a normal carryover inventory) as estimated by the Secretary for such area for the calendar year during which the larger part of the sugar or liquid sugar from such crop normally would be marketed.

and

Whereas the Secretary of Agriculture, on September 15, 1938, estimated the amount (in terms of planted acreage) of sugar beets required to be processed from the 1939 crop to enable the beet sugar area to fill its quota (and provide a normal carryover inventory), estimated for the calendar year during which the larger part of the sugar from such crop normally would be marketed, to be 1,030,000 acres:

Now, therefore, I, H. A. Wallace, Secretary of Agriculture, do hereby determine that the proportionate share of sugar beets in terms of planted acres for any farm in the beet sugar area for the 1939 crop shall be the acreage established as follows:

A. In a district in which the total acreage requested for proportionate shares does not exceed the acreage allocation hereinafter made for such district, the proportionate share shall be the acreage requested.

B. In a district in which the total acreage requested for proportionate shares exceeds the acreage allocation hereinafter made for such district, the proportionate share for a farm for which a proportionate share is requested shall be calculated upon the basis of the average acreage of sugar beets planted on the farm during a period of not less than three and not more than ten consecutive years, including the year 1938 (the same years to be included for all farms in the district), and from the figure so obtained there shall be deducted (a) the acreage obtained by multiplying such average acreage for the farm by the percentage that the total of such average acreages for all farms in the district exceeds the district allocation, (b) the acreage by which the average acreage for the farm, as adjusted in (a) above, exceeds the acreage requested for the farm, and (c) any acreage by which the average acreage for the farm, as adjusted in (a) and (b) above, exceeds the ability to produce sugar beets, as hereinafter defined; and to the figure thus obtained there shall be added any acreage apportioned to the farm from the amount by which the total of such figures for all farms in the district is less than the acreage allocated to the district. In making such apportionment there shall be taken into consideration, first, requests from small producers, second, requests from new producers who are not small producers, and, third, requests from producers, other than small or new producers, requesting acreages in excess of their average acreage as adjusted in (a) above, and in all three cases consideration shall be given to ability to produce sugar beets, as measured by availability and suitability of land, area of available fields, availability of irrigation water, adequate drainage, availability of production and marketing facilities, and the production experience of the producer.

Provided, however, That the total of the proportionate shares established for farms by districts shall not be in excess of the following:

State and District	*Acres*
California:	
Alvarado, Tracy, and Hamilton City	37,628
Manteca and Woodland	52,044
Salinas	23,651
Clarksburg	14,954
Betteravia	13,834
Oxnard	18,071
Los Alamitos	6,001
Dyer (Santa Ana)	7,712
Colorado:	
Brush	8,860
Brighton	10,779
Eaton	16,903
Fort Collins	13,902
Fort Morgan	13,363
Fort Lupton	11,326
Greeley	13,264
Longmont	16,517
Loveland	11,015
Ovid	16,158
Sterling	14,348
Windsor	11,474
Sugar City	6,764
Rocky Ford	17,203
Swink	10,257
Delta Gr. Junct.	8,598

State and District	*Acres*
Idaho:	
Upper Snake	31,260
Twin Falls	14,928
Burley-Rupert	12,617
Preston	7,921
Indiana:	
Decatur	14,228
Iowa:	
Mason City	14,183
Kansas:	
Garden City	10,310
Michigan:	
Alma	11,901
Caro	12,418
Croswell	10,493
Lansing	9,700
Saginaw	11,653
Sebewaing	11,366
Holland	5,436
St. Louis	10,595
Bay City	16,687
Mt. Clemens	8,661
Mt. Pleasant	11,769
Blissfield	11,414
Menominee	7,532
Minnesota:	
East Grand Forks	26,483
Chaska	14,089
Montana:	
Billings	26,735
Chinook	14,577
Missoula	11,585
Sidney	17,485
Hardin	11,638
Nebraska:	
Bayard	13,066
Gering	10,774
Lyman	7,172
Minatare	10,742
Mitchell	7,892
Scottsbluff	10,029
Grand Island	12,328
Ohio:	
Findlay	11,743
Fremont	10,920
Ottawa	9,208
Paulding	10,442
Oregon: Nyssa	16,322
South Dakota: Belle Fourche	10,513
Utah:	
Brigham-Garland	10,702
Spanish Fork and West Jordan	13,747
Centerfield	6,766
Ogden	7,035
Lewiston	11,200
Layton	5,723
Washington:	
Bellingham	3,118
Toppenish	14,310
Wisconsin:	
Green Bay	7,125
Janesville	6,893
Wyoming:	
Wheatland	7,825
Lovell	11,566
Torrington	20,935
Worland	13,474
Sheridan	6,140
Total	1,030,000

For the purposes of this determination:

1. A producer shall be deemed to be a small producer if in 1939 he operates a farm for which the proportionate share requested is less than 35% of the average planted sugar beet acreage per farm for the district in which such farm is included.

2. A producer shall be deemed to be a new producer if in 1939 he operates a farm on which sugar beets have not been planted during the period used as the measure of history of planted sugar beet acreage for the district in which such farm is included.

3. A district shall be deemed to include the farms with respect to which the operators signify intention to contract for the production of sugar beets for delivery to the beet sugar factory or factories identifying the district (specified above), and shall include only the farms located within the territory in which sugar beets are normally contracted for delivery to such factory or factories.

The proportionate shares for farms shall be established in accordance with this determination by a committee of sugar beet producers designated for the district by the appropriate Division of the Agricultural Adjustment Administration.

Done at Washington, D. C., this 23d day of December 1938. Witness my hand and the seal of the Department of Agriculture.

[SEAL] H. A. WALLACE,
Secretary of Agriculture.

[F. R. Doc. 38-3908; Filed, December 27, 1938; 12:18 p. m.]

TITLE 17—COMMODITY AND SECURITIES EXCHANGES

SECURITIES AND EXCHANGE COMMISSION

PUBLIC UTILITY HOLDING COMPANY ACT OF 1935

AMENDMENT OF RULE U-12F-1 [1]

Pursuant to authority conferred upon it by Sections 12 (f), 20 (a) and 27 (a) of the Public Utility Holding Company Act of 1935, and deeming it appropriate in the public interest and for the protection of investors and consumers, the Securities and Exchange Commission hereby amends subparagraph (2) of paragraph (e) of Rule U-12F-1 [Sec. 15. U-12F-1] entitled "Sale of Public Utility Securities and Utility Assets to Associate Companies or Affiliates" by striking out of said sub-paragraph (2) the words "April 15, 1938," and inserting in lieu thereof "December 19, 1938."

Effective December 24, 1938.

By the Commission.

[SEAL] FRANCIS P. BRASSOR,
Secretary.

[F. R. Doc. 38-3904; Filed, December 27, 1938; 11:12 a. m.]

[1] 3 F. R. 2897 DI.

PUBLIC UTILITY HOLDING COMPANY ACT OF 1935

AMENDMENT OF RULE U-17C-11 [1]

Pursuant to authority granted by the Public Utility Holding Company Act of 1935 and particularly Sections 17 (c) and 20 (a) thereof and finding that such action will not adversely affect the public interest or the interest of investors or consumers and is appropriate to carry out the provisions of said Act, the Securities and Exchange Commission hereby amends Rule U-17C-11 [Sec. 15.U-17C-11] entitled "Independent Officers or Directors" by striking out of paragraph (c) of said rule the words "January 1, 1939," and by inserting in lieu thereof "April 1, 1939."

Effective December 31, 1938.

By the Commission.

[SEAL] FRANCIS P. BRASSOR,
Secretary.

[F. R. Doc. 38-3903; Filed, December 27, 1938; 11:12 a. m.]

TITLE 18—CONSERVATION OF POWER

FEDERAL POWER COMMISSION

[Order No. 57]

DIRECTING NATURAL-GAS COMPANIES HAVING AGREEMENTS PROVIDING FOR PERIODIC CHANGES IN RATES TO SUBMIT INFORMATION AND DATA SPECIFIED IN PROVISIONAL RULES AND REGULATIONS

DECEMBER 20, 1938.

Commissioners: Clyde L. Seavey, Acting Chairman; Claude L. Draper, Basil Manly, John W. Scott.

It appearing to the Commission that:

(a) Part 54, Section 54.3 C [2] of the Provisional Rules of Practice and Regulations Under the Natural Gas Act, provides that all rate schedules making a change in any rate, charge, classification or service, on file with the Commission, or in any rule, regulation or contract relating thereto, shall be filed with the Commission not less than thirty days prior to the proposed effective date thereof, unless a shorter period of time is authorized by the Commission; and as to each proposed change there shall be submitted to the Commission at the same time—(1) a statement outlining the reasons for the proposed change and the desirability thereof; (2) pertinent data supporting the statements in (1) above; and (3) an estimate of the probable sales and revenue under the rate after the proposed change becomes effective, for a period of 12 months thereafter;

(b) In many instances agreements of natural-gas companies, filed pursuant to Section 4 (c) of the Natural Gas Act, contain provisions whereby changes in rate schedules are to become effective periodically upon dates subsequent to the filing of such agreements, and in con-

[1] 2 F. R. 2197 (2555 DI).
[2] 3 F. R. 1687 DI.

nection with such changes certain natural-gas companies have not submitted the information and data specified in Part 54, Section 54.3 C of the Provisional Rules of Practice and Regulations Under the Natural Gas Act;

The Commission *orders* that:

Each natural-gas company having on file with the Commission an agreement or agreements providing for periodic change or changes therein, to become effective subsequent to the date of filing of such agreement or agreements shall, within not less than 30 days prior to the effective date of such change or changes, submit to the Commission the information and data specified in Part 54, Section 54.3 C of the Provisional Rules of Practice and Regulations Under the Natural Gas Act.

By the Commission.

[SEAL] LEON M. FUQUAY, *Secretary.*

[F. R. Doc. 38-3899; Filed, December 27, 1938; 11:10 a. m.]

Notices

CIVIL AERONAUTICS AUTHORITY.

[Docket No. 26-406 (A)-1]

PETITION BY INLAND AIR LINES, INC. FOR AN ORDER FIXING AND DETERMINING FAIR AND REASONABLE RATES OF COMPENSATION FOR TRANSPORTATION OF MAIL BY AIRCRAFT OVER AIR MAIL ROUTE NO. 35 AND FOR SERVICES CONNECTED THEREWITH

NOTICE OF HEARING

DECEMBER 23, 1938.

The above-entitled proceeding is assigned for public hearing on January 10, 1939, 10 o'clock a. m. (eastern standard time) at the offices of the Civil Aeronautics Authority (Hearing Room No. 5044), in Washington, D. C., before the Authority.

By the Authority:

[SEAL] PAUL J. FRIZZELL, *Secretary.*

[F. R. Doc. 38-3905; Filed, December 27, 1938; 11:53 p. m.]

[Docket No. 6-406(A)-1]

APPLICATION BY PAN AMERICAN AIRWAYS COMPANY TO FIX AND DETERMINE FAIR AND REASONABLE RATES OF COMPENSATION FOR TRANSPORTATION OF MAIL BY AIRCRAFT, AND FACILITIES USED AND USEFUL THEREFOR, AND SERVICES CONNECTED THEREWITH, ON ROUTE BETWEEN SAN FRANCISCO, CALIFORNIA, AND HONG KONG, CHINA

NOTICE OF HEARING

DECEMBER 27, 1938.

The above-entitled proceeding is assigned for public hearing on January 16, 1939, 10 o'clock a. m. (eastern standard time) at the offices of the Civil Aeronautics Authority (Hearing Room No. 5044), in Washington, D. C., before the Authority.

By the Authority:

[SEAL] PAUL J. FRIZZELL, *Secretary.*

[F. R. Doc. 38-3906; Filed, December 27, 1938; 11:53 a. m.]

SECURITIES AND EXCHANGE COMMISSION.

United States of America—Before the Securities and Exchange Commission

At a regular session of the Securities and Exchange Commission, held at its office in the City of Washington, D. C., on the 22nd day of December, A. D. 1938.

[File No. 32-111]

IN THE MATTERS OF ARKANSAS WESTERN GAS COMPANY AND SOUTHERN UNION GAS COMPANY

ORDER

Arkansas Western Gas Company, a subsidiary of Southern Union Gas Company, a registered holding company, having filed applications pursuant to Section 6 (b) of the Public Utility Holding Company Act of 1935, and Rule U-12C-1 promulgated thereunder, in respect of (1) the issue and sale of $750,000 principal amount of its First Mortgage, Series A, Fifteen Year 6% Sinking Fund Bonds, (2) the issue and sale of 2,500 shares of its 6% Cumulative Preferred Stock, par value $50 per share, in exchange for $125,000 principal amount of its Five Year 7% Gold Debentures, and (3) the acquisition of $125,000 principal amount of its 7% Debentures, and having requested an order permitting a declaration to become effective pursuant to Section 7 of the Act regarding such "exercise of any privilege or right to alter the priorities, preferences, voting power or other rights of an outstanding security of such company" within the meaning of Section 6 (a) (2) of the Act as may be involved in (a) the reduction in the stated value of its no par common stock from $80 to $35 per share, and (b) changes in voting power incident to the issuance of the above-designated preferred stock; and

Southern Union Gas Company, a registered holding company, having filed an application, pursuant to Rule U-12D-1, for approval of the sale of said Debentures to Arkansas Western Gas Company; and

Public hearings on said matters having been held[1] after appropriate notice and the Commission having considered the record in these matters and having made and filed its findings and opinion herein:

It is ordered, That the applications filed pursuant to Section 6 (b) of the Act and Rule U-12C-1 by Arkansas Western Gas Company be granted, subject, however, to the following terms and conditions: (1) that the issue, sale, and exchange of said securities by Arkansas Western Gas Company shall be effected in accordance with the terms and conditions of, and for the purposes represented by, said applications; (2) that if the express authorization of the issue and sale of said bonds and preferred stock by the Department of Public Utilities of the State of Arkansas shall be revoked or otherwise terminated, the exemption provided in respect of such issue and sale shall immediately terminate without further order of this Commission; and (3) that within ten days after the issue and sale, and the acquisition, of said securities the applicant shall file with this Commission a Certificate of Notification showing that such issue and sale, and such acquisition have been effected in accordance with the terms and conditions of, and for the purposes represented by, said applications.

It is further ordered, That declarations regarding such alterations in the priorities, preferences, voting power or other rights as are involved in the reduction in stated value of Arkansas Western Gas Company's no par common stock from $85 to $35; and in the issuance by Arkansas Western Gas Company of 2,500 shares of its 6% Cumulative Preferred Stock, par value $50 per share, be and become effective forthwith, on the condition, however, that such matters shall be performed in all respects as set forth in said applications.

It is further ordered, That the application of Southern Union Gas Company, pursuant to Rule U-12D-1, is hereby approved, subject, however, to the condition that such sale shall be effected in compliance with and for the purposes represented by said application, and upon the further condition that Southern Union Gas Company shall file with this Commission, within ten days after the sale of said debentures, a Certificate of Notification to that effect.

By the Commission.

[SEAL] FRANCIS P. BRASSOR, *Secretary.*

[F. R. Doc. 38-3902; Filed, December 27, 1938; 11:12 a. m.]

[1] 3 F. R. 2601 DI.

United States of America—Before the Securities and Exchange Commission

At a regular session of the Securities and Exchange Commission held at its office in the City of Washington, D. C., on the 21st day of December, A. D. 1938.

[File No. 43-119]

IN THE MATTER OF MONONGAHELA WEST PENN PUBLIC SERVICE COMPANY AND AMERICAN WATER WORKS AND ELECTRIC COMPANY, INCORPORATED

ORDER

Monongahela West Penn Public Service Company, a subsidiary of American Water Works and Electric Company, Incorporated, a registered holding company, having filed a declaration pursuant to Section 7 of the Public Utility Holding Company Act of 1935 regarding the reduction of the par value of its common stock from $25 per share to $15 per share and regarding the issue and sale of 200,000 additional shares of its common stock having such reduced par value; and said American Water Works and Electric Company, Incorporated, having filed an application pursuant to Section 10 (a) (1) of said Act for approval of the acquisition of such additional shares for the consideration of $3,000,000 or $15 per share;

Public hearings having been held [1] on the above matters after appropriate notice; and the Commission having made and filed its findings herein:

It is ordered, That said declaration by Monongahela West Penn Public Service Company be and become effective forthwith, subject however to the following conditions: That no charges (other than those required by other regulatory bodies having exclusive jurisdiction in the premises) shall be made to the capital surplus resulting from the reduction in the par value of declarant's stock unless prior notice of the making of such charge be given to this Commission, in which event the Commission reserves jurisdiction, after notice and opportunity for hearing, to disapprove such charge on the basis of the record herein and any additional evidence that may be adduced by any interested party; and in the event that the Commission shall notify declarant to show cause why such charge should not be approved, the charge in question shall not be made until expressly authorized by order of this Commission;

It is further ordered, That the application of American Water Works and Electric Company, Incorporated, be and the same hereby is approved.

By the Commission.

[SEAL] FRANCIS P. BRASSOR, *Secretary.*

[F. R. Doc. 38-3900; Filed, December 27, 1938; 11:11 a. m.]

[1] 3 F. R. 2879 DI.

United States of America—Before the Securities and Exchange Commission

At a regular session of the Securities and Exchange Commission held at it office in the City of Washington, D. C., on the 20th day of December, A. D. 1938.

[File No. 43-170]

IN THE MATTER OF PENNSYLVANIA POWER COMPANY, THE COMMONWEALTH & SOUTHERN CORPORATION

ORDER

Pennsylvania Power Company, a subsidiary of The Commonwealth & Southern Corporation, a registered holding company, having filed an application and declarations pursuant to Sections 6 (b) and 7 of the Public Utility Holding Company Act of 1935 regarding the issue and sale of 42,000 shares of its $5 cumulative no-par preferred stock, 10,000 shares of its no-par common stock, and its 1½% promissory note in the principal amount of $3,000,000;

The Commonwealth & Southern Corporation having filed an application pursuant to Section 10 of the Act for the approval of the acquisition by it of the aforesaid 10,000 shares of no-par common stock to be acquired at the stated value of $300,000;

A joint hearing having been held [1] on said applications and declarations after appropriate notice, and the Commission having considered the record in this matter and having made and filed its findings herein;

It is ordered, That the issue and sale of 42,000 shares of such preferred stock be and the same hereby are exempted from the provisions of Section 6 (a) of the Act;

It is further ordered, That the declarations with respect to the aforesaid 10,000 shares of common stock and the promissory note in the principal amount of $3,000,000 be and become effective forthwith;

It is further ordered, That the acquisition of the aforesaid 10,000 shares of common stock by The Commonwealth & Southern Corporation is hereby approved; the Commission, however, reserves jurisdiction as to the amount at which The Commonwealth & Southern Corporation carries its investment in the common capital stock of Pennsylvania Power Company;

It is further ordered, That this order be subject to the following terms and conditions:

(1) That all acts in connection with said declarations and applications shall be performed in all respects as set forth in, and for the purposes represented by, said applications and declarations; and

(2) That in the event that the order of the Pennsylvania Public Service Commission expressly authorizing the issuance of the preferred stock shall be revoked, rescinded, or otherwise terminated, the exemption granted herein shall immediately terminate without further notice or order; and

(3) That within ten days after the issuance of the securities referred to herein, and the acquisition of the common stock, the declarant and applicants shall, respectively, file with this Commission certificates of notification showing that such issue and sale and acquisition have been effected in accordance with the terms and conditions of, and for the purposes represented by, the declarations and applications.

By the Commission.

[SEAL] FRANCIS P. BRASSOR, *Secretary.*

[F. R. Doc. 38-3901; Filed, December 27, 1938; 11:11 a. m.]

[1] 3 F. R. 2859 DI.